

PARTNERSHIP



**PARTNERSHIP HEALTHPLAN OF CALIFORNIA (PHC)  
PHARMACY UPDATE**

**NUMBER 03 - 07**

**November 2007**

**Introduction**

Please keep these updates on file in your Pharmacy Procedure Manual as they will contain important information regarding formulary changes and additions, plan parameter changes, billing procedures, the Treatment Authorization Request (TAR) process and other necessary information. Please refer to your Pharmacy Procedure Manual as most of the topics contained in this update are explained in detail in the Manual. If you have not received your updated copy of the Pharmacy Procedure Manual, you may download it from the PHC website at [www.partnershiphp.org](http://www.partnershiphp.org) or contact the Pharmacy Department at (707) 863-4414 to request a copy.

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## **Subacute Bacterial Endocarditis (SBE) prophylaxis**

Recently the American Heart Association issued new endocarditis prophylaxis guidelines. Patients with mitral valve prolapse, aortic stenosis/insufficiency are no longer recommended to receive prophylaxis unless they have had endocarditis or have a prosthetic valve. Please see the following guideline attached (Attachment A).

## **Treatment Authorization Request (TAR)/ Coverage Determination Form (CDF) processing.**

Please include the prescribing physician's name, telephone and FAX number when submitting the TAR/CDF. If PHC defers the TAR/CDF for more information, we can direct those requests to the appropriate prescribing physician.

## **5 day emergency supply:**

PHC's Pharmacy policies allow patients to receive a 5 day fill for any medication even a non-formulary drug in an emergency situation. Prescribers are reminded to write "emergency fill" on the prescription if the medication is for an emergency. Emergency authorizations for TAR's outside of PHC's normal business hours may be requested from MedImpact (PHC's contracted Pharmacy Benefits Manager) at (800) 788-2949, who may authorize up to a 5 day supply, pending further authorization by PHC.

## **Medication Therapy Management (MTM) for PartnershipAdvantage (PA) members: Outcomes Targeted Intervention Program (TIP™)**

PHC has elected to utilize community pharmacists as the providers of MTM services in our PartnershipAdvantage Prescription Drug Plan. Outcomes Pharmaceutical Health Care® (Outcomes®) is administering the MTM program.

A subgroup of PA members is eligible for a full menu of face-to-face MTM services.

Through the TIP, Outcomes works to assist pharmacists with the identification of potential MTM services that can be delivered to eligible PA members. These interventions may focus on use of potentially inappropriate medications in the elderly, or therapeutic duplication. In addition, interventions targeting chronic diseases such as diabetes, COPD, and cardiovascular disease are focused on guideline-recommended therapy and quality metrics defined by HEDIS and NCQA initiatives.

On at least a quarterly basis, Outcomes distributes TIPs to the dispensing pharmacy network via mail and/or fax. Targeted interventions if successfully completed will be reimbursed the stated fees on the TIPs. No contract is required to participate in the TIP program. In addition, pharmacists are also not required to complete the training program to participate in TIPs.

If your pharmacy has received a TIP via fax or mail, please review the intervention which outlines one or more patient-specific potential drug therapy problems. Follow the stepwise instructions for completing the form and fax or mail the completed form(s) back to Outcomes at:

### ***BY MAIL:***

OUTCOMES PHARMACEUTICAL HEALTH CARE  
601 E LOCUST, SUITE 200  
DES MOINES, IA 50309-1946

***BY FAX:*** 515-237-0002

Pharmacists that have completed Outcomes provider requirements may also bill for a number of additional MTM services such as patient education & monitoring, comprehensive medication reviews and OTC consultations.

If you are interested in participating in the full MTM program, please visit the Outcomes website at [www.getoutcomes.com](http://www.getoutcomes.com) and go to Pharmacist section and select "Pharmacy Contracting or Pharmacist Training" sections or

contact an Outcomes representative at 515.237.0001.

### **Prior Authorization (PA) Criteria**

#### **Addition/Changes:**

##### **Neupogen (filgrastim) and Neulasta (pegfilgrastim):**

Use of Neupogen (filgrastim) will require PA and be limited to treatment in members with a documented history of neutropenia secondary to cancer chemotherapy when prescribed by an oncologist and in members with congenital neutropenia, cyclic neutropenia or idiopathic neutropenia.

Use of Neulasta (pegfilgrastim) will be limited to treatment in members with a document history of neutropenia secondary to cancer chemotherapy when prescribed by an oncologist.

##### **Erythropoietin Stimulating Agents (ESA):**

In March 2007, results of studies prompted the FDA to issue ESA boxed warnings indicating a higher incidence of mortality, thromboembolic events and tumor progression in patients using ESA compared to control. The findings from these studies underscored that target Hgb should not exceed 12 g/dL.

In response to these boxed warnings, the Centers for Medicare & Medicaid Services (CMS) announced its final national coverage determination (NCD) for the use of ESA in cancer and related neoplastic conditions effective July 30, 2007

PHC Prior authorization Criteria for ESA were revised to lower threshold limits for Hgb/Hct at less than 12 gm/dL (36%) and made effective September 2007.

Effective 12/1/07, the PA criteria for Hgb/Hct threshold limit for Oncology patients receiving cancer chemotherapy and for patients with low grade myelodysplasia not receiving chemotherapy is less than 10 gm/dL (30%).

The complete revised ESA Prior authorization criteria guideline is attached (Attachment B).

### **Formulary Reminders:**

#### **Chantix (varenicline):**

Effective 9/1/07, Chantix (varenicline) was approved for smoking cessation use limited to 12 weeks in duration. A TAR/CDF will be needed with documentation of enrollment in a smoking cessation behavioral intervention program if therapy continues beyond the initial 12 weeks of treatment. Information regarding classes (offered in multiple languages) can be obtained at (1-800- NO-BUTTS).

#### **Lamictal (lamotrigine)**

Effective 11/01/07, Lamictal (lamotrigine) continues as a non-formulary drug item with a limit of ½ tablet substitution for the 25 mg, 50 mg and 100 mg doses.

As a result of the October 4, 2007 Pharmacy & Therapeutics (P&T) Committee meeting the attached formulary additions and changes were accepted. Effective date for these additions and changes will be **November 1, 2007**

# New AHA SBE Prophylaxis Guidelines

April 2007

(1) Who needs prophylaxis? **Only** those with:

- a. H/O endocarditis
- b. Prosthetic valve
- c. Cardiac transplant with secondary valvulopathy
- d. Congenital heart disease
  - i. Unrepaired cyanotic CHD
  - ii. Repaired cyanotic CHD if prosthetic material or device used (1<sup>st</sup> 6 months after procedure)

(2) For Which Procedures:

- a. All dental procedures involving manipulation of gingival tissue or the periapical region of teeth or surgical perforation of the oral mucosa.
- b. Respiratory tract – incision or bx of respiratory mucosa including tonsillectomy or adenoidectomy.

P.S.

- *Not* needed for GI or GU tract procedures.
- *Not* needed for routine bronchoscopy without biopsy.

## Regimens for a Dental Procedure

Situation	Agent	Regimen: <b>Single</b> Dose 30 to 60 min Before Procedure	
		Adults	Children
Oral	Amoxicillin	2 g	50 mg/kg
Unable to take oral medication	Ampicillin	2 g IM or IV	50 mg/kg IM or IV
	<b>OR</b> Cefazolin or ceftriaxone	1 g IM or IV	50 mg/kg IM or IV
Allergic to penicillins or ampicillin – oral	Cephalexin*+	2 g	50 mg/kg
	<b>OR</b> Clindamycin	600 mg	20 mg/kg
	<b>OR</b> Azithromycin or clarithromycin	500 mg	15 mg/kg
Allergic to penicillins or ampicillin	Cefazolin or ceftriaxone+	1 g IM or IV	50 mg/kg IM or IV
	<b>OR</b> Clindamycin	600 mg IM or IV	20 mg/kg IM or IV

IM indicates intramuscular; IV, intravenous.

\*Or other first- or second-generation oral cephalosporin in equivalent adult or pediatric dosage.

+Cephalosporins should not be used in an individual with a history of anaphylaxis, angioedema, or urticaria with penicillins or ampicillin.

For more information visit:

<http://circ.ahajournals.org/cgi/content/full/116/15/1736>

**PRIOR AUTHORIZATION  
CRITERIA GUIDELINES  
ADDITIONS/CHANGES  
December 1, 2007**

BRAND NAME	GENERIC NAME	CURRENT PA CRITERIA	New PA CRITERIA
Lamictal	(lamotrigine)	<p>Medi-Cal: New starts only. Use in patients with diagnosis for seizure disorders or bipolar disorder with trial and failure of first line therapy (lithium, Depakote)</p> <p>Partnership Advantage: New starts only. Use in patients with diagnosis for seizure disorders or bipolar disorder with trial and failure of first line therapy (lithium, Depakote)</p>	<p>Medi-Cal: New starts only. Use in patients with diagnosis for seizure disorders or bipolar disorder with trial and failure of first line therapy (lithium, Depakote)</p> <p>½ tablet substitution</p> <p>-25 mg (chewable) : use ½ tablet 50 mg</p> <p>-100 mg use ½ tablet of 200 mg</p> <p>- 50 mg use ½ tablet of 100 mg</p> <p>Partnership Advantage: New starts only. Use in patients with diagnosis for seizure disorders or bipolar disorder with trial and failure of first line therapy (lithium, Depakote)</p>
Neupogen	(filgrastim)	Treatment in members with neutropenia secondary to chemotherapy and in members with congenital neutropenia, cyclic neutropenia or idiopathic neutropenia. No PA required if supplied and administered in a physician's office or outpatient facility in conjunction with chemotherapy.	Treatment in members with documented history of neutropenia secondary to cancer chemotherapy when prescribed by an oncologist and in members with congenital neutropenia, cyclic neutropenia or idiopathic neutropenia.
Neulasta	(pegfilgrastim)	None	Treatment in members with documented history of neutropenia secondary to cancer chemotherapy when prescribed by an oncologist
Epogen, Procrit	(Erythropoietin)	<p><b>Chronic Kidney Disease (CKD) in dialysis centers</b> – No PA required – documentation must be submitted on the Clinical Justification Worksheet.</p> <p><b>CKD – Erythropoietin not administered in dialysis center</b> – PA required</p> <ul style="list-style-type: none"> <li>• Maintain Hgb/Hct between 11 and 12 g/Dl (33% and</li> </ul>	<p><b>Chronic Kidney Disease (CKD) in dialysis centers</b> – No PA required – documentation must be submitted on the Clinical Justification Worksheet.</p> <p><b>CKD – Erythropoietin not administered in dialysis center</b> – PA required</p> <ul style="list-style-type: none"> <li>• Maintain Hgb/Hct between 11 and 12 g/Dl (33% and</li> </ul>

**Attachment B**

		<p>36%) based on a recent measurement within the last month or a rolling average for 37.5 or less in the past 3 months.</p> <ul style="list-style-type: none"> <li>• Appropriate indications for administering Epoetin alfa if the Hgb/Hct is &gt;12/36 include:             <ul style="list-style-type: none"> <li>○ Reduction of the dose by 25%</li> <li>○ A dose of 1000 units or less.</li> </ul> </li> <li>Or</li> <li>○ Co-Morbid conditions such as CHF/Pulmonary Disease</li> <li>○</li> </ul> <p><b>Oncology</b> – Anemia associated with malignancy, chemotherapy or Myelodysplastic syndrome – PA required</p> <ul style="list-style-type: none"> <li>• For pts receiving cancer chemotherapy and for pts with low grade myelodysplasia not receiving chemotherapy – Hgb/Hct less than 12 g/dl (36%) within the previous month</li> <li>• For pts with anemia associated with other hematologic malignancies in the absence of chemotherapy – trial and failure of conventional therapy for anemia</li> <li>• Starting dosage – 150 U/kg three times per week.</li> </ul> <p><b>Elective, noncardiac, nonvascular surgery when patient is unable or unwilling to donate autologous blood</b> – PA required</p> <ul style="list-style-type: none"> <li>• Hgb/Hct between 10 and 12 g/dl (30-36%) and pt is unwilling or unable to donate autologous blood; the recommended dose of recombinant human erythropoietin is 300 units/kg/day subcutaneously for 10 days prior to, on the day of, and for four days post-surgery. An alternate dose schedule is 600</li> </ul>	<p>36%) based on a recent measurement within the last month or a rolling average for 37.5 or less in the past 3 months.</p> <ul style="list-style-type: none"> <li>• Appropriate indications for administering Epoetin alfa if the Hgb/Hct is &gt;12/36 include:             <ul style="list-style-type: none"> <li>○ Reduction of the dose by 25%</li> <li>○ A dose of 1000 units or less.</li> </ul> </li> <li>Or</li> <li>○ Co-Morbid conditions such as CHF/Pulmonary Disease</li> <li>○</li> </ul> <p><b>Oncology</b> – Anemia associated with malignancy, chemotherapy or Myelodysplastic syndrome – PA required</p> <ul style="list-style-type: none"> <li>• For pts receiving cancer chemotherapy and for pts with low grade myelodysplasia not receiving chemotherapy – Hgb/Hct less than 10 g/dl (30%) within the previous month</li> <li>• For pts with anemia associated with other hematologic malignancies in the absence of chemotherapy – trial and failure of conventional therapy for anemia</li> <li>• No epoetin alfa for anemia associated with radiotreatment</li> <li>• Starting dosage – 150 U/kg three times per week.</li> </ul> <p><b>Elective, noncardiac, nonvascular surgery when patient is unable or unwilling to donate autologous blood</b> – PA required</p> <ul style="list-style-type: none"> <li>• Hgb/Hct between 10 and 12 g/dl (30-36%) and pt is unwilling or unable to donate autologous blood; the recommended dose of recombinant human erythropoietin is 300 units/kg/day subcutaneously for 10 days prior</li> </ul>
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		<p>units/kg of recombinant human erythropoietin subcutaneously in once-a-week doses (21, 14 and 7 days prior to surgery) plus a fourth dose given on the day of surgery</p> <p><b>Anti-retroviral therapy for HIV infected patients – PA required</b></p> <ul style="list-style-type: none"> <li>• Case by case review. Co-morbid conditions.</li> <li>• Hgb/Hct between 10 and 12 g/dl (30-36%) and a serum erythropoietin of less than 500 Mu/ml.</li> </ul> <p><b>Note –</b> In all cases the cause of the anemia is not due to correctable/treatable factors such as:</p> <ul style="list-style-type: none"> <li>▪ Iron deficiency (it is recognized that patients on EPO may still require supplemental iron therapy.)</li> <li>▪ Underlying infectious or inflammatory processes.</li> <li>▪ Occult blood loss.</li> <li>▪ Underlying hematologic diseases (i.e., thalassemia)</li> <li>▪ Vitamin deficiencies: (i.e., folic acid or vitamin B12)</li> <li>• Hemolysis.</li> </ul>	<p>to, on the day of, and for four days post-surgery. An alternate dose schedule is 600 units/kg of recombinant human erythropoietin subcutaneously in once-a-week doses (21, 14 and 7 days prior to surgery) plus a fourth dose given on the day of surgery</p> <p><b>Anti-retroviral therapy for HIV infected patients – PA required</b></p> <ul style="list-style-type: none"> <li>• Case by case review. Co-morbid conditions.</li> <li>• Hgb/Hct between 10 and 12 g/dl (30-36%) and a serum erythropoietin of less than 500 Mu/ml.</li> </ul> <p><b>Note –</b> In all cases the cause of the anemia is not due to correctable/treatable factors such as:</p> <ul style="list-style-type: none"> <li>▪ Iron deficiency (it is recognized that patients on EPO may still require supplemental iron therapy.)</li> <li>▪ Underlying infectious or inflammatory processes.</li> <li>▪ Occult blood loss.</li> <li>▪ Underlying hematologic diseases (i.e., thalassemia)</li> <li>▪ Vitamin deficiencies: (i.e., folic acid or vitamin B12)</li> <li>• Hemolysis.</li> </ul>
<p>Aranesp</p>	<p>Darbepoetin alfa</p>	<p><b>Chronic Kidney Disease (CKD) in dialysis centers –</b> No PA required – documentation must be submitted on the Clinical Justification Worksheet.</p> <p><b>CKD – Darbepoetin not administered in dialysis center –</b> PA required</p>	<p><b>Chronic Kidney Disease (CKD) in dialysis centers –</b> No PA required – documentation must be submitted on the Clinical Justification Worksheet.</p> <p><b>CKD – Darbepoetin not administered in dialysis center –</b> PA required</p>

**Attachment B**

		<ul style="list-style-type: none"> <li>• Maintain Hgb/Hct between 11 and 12 g/Dl (33% and 36%) based on a recent measurement within the last month or a rolling average for 37.5 or less in the past 3 months.</li> <li>• Appropriate indications for administering darbepoetin if the Hgb/Hct is &gt;12/36 include:             <ul style="list-style-type: none"> <li>○ Reduction of the dose by 25%</li> <li>○ A dose of 5 mcg or less.</li> </ul> </li> <li>Or</li> <li>○ Co-Morbid conditions such as CHF/Pulmonary Disease</li> <li>○</li> </ul> <p><b>Oncology</b> – Anemia associated with malignancy, chemotherapy or Myelodysplastic syndrome – PA required</p> <ul style="list-style-type: none"> <li>• For pts receiving cancer chemotherapy and for pts with low grade myelodysplasia not receiving chemotherapy – Hgb/Hct less than 12 g/dl (36%) within the previous month</li> <li>• For pts with anemia associated with other hematologic malignancies in the absence of chemotherapy – trial and failure of conventional therapy for anemia</li> <li>• Starting dosage – 2.25 mcg/kg per week.</li> </ul> <p><b>Elective, noncardiac, nonvascular surgery when patient is unable or unwilling to donate autologous blood</b> – PA required</p> <ul style="list-style-type: none"> <li>• Hgb/Hct between 10 and 12 g/dl (30-36%) and pt is unwilling or unable to donate autologous blood.</li> </ul> <p><b>Anti-retroviral therapy for HIV infected patients</b> – PA required</p> <ul style="list-style-type: none"> <li>• Case by case review. Co-morbid</li> </ul>	<ul style="list-style-type: none"> <li>• Maintain Hgb/Hct between 11 and 12 g/Dl (33% and 36%) based on a recent measurement within the last month or a rolling average for 37.5 or less in the past 3 months.</li> <li>• Appropriate indications for administering darbepoetin if the Hgb/Hct is &gt;12/36 include:             <ul style="list-style-type: none"> <li>○ Reduction of the dose by 25%</li> <li>○ A dose of 5 mcg or less.</li> </ul> </li> <li>Or</li> <li>○ Co-Morbid conditions such as CHF/Pulmonary Disease</li> <li>○</li> </ul> <p><b>Oncology</b> – Anemia associated with malignancy, chemotherapy or Myelodysplastic syndrome – PA required</p> <ul style="list-style-type: none"> <li>• For pts receiving cancer chemotherapy and for pts with low grade myelodysplasia not receiving chemotherapy – Hgb/Hct less than 10 g/dl (30%) within the previous month</li> <li>• For pts with anemia associated with other hematologic malignancies in the absence of chemotherapy – trial and failure of conventional therapy for anemia</li> <li>• No darbepoetin for anemia associated with radiotherapy</li> <li>• Starting dosage – 2.25 mcg/kg per week.</li> </ul> <p><b>Elective, noncardiac, nonvascular surgery when patient is unable or unwilling to donate autologous blood</b> – PA required</p> <ul style="list-style-type: none"> <li>• Hgb/Hct between 10 and 12 g/dl (30-36%) and pt is unwilling or unable to donate autologous blood.</li> </ul> <p><b>Anti-retroviral therapy for HIV infected</b></p>
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		<p>conditions.</p> <ul style="list-style-type: none"> <li>• Hgb/Hct between 10 and 12 g/dl (30-36%) and a serum erythropoietin of less than 500 Mu/ml.</li> </ul> <p><b>Note</b> – In all cases the cause of the anemia is not due to correctable/treatable factors such as:</p> <ul style="list-style-type: none"> <li>▪ Iron deficiency (it is recognized that patients on darbepoetin may still require supplemental iron therapy.)</li> <li>▪ Underlying infectious or inflammatory processes.</li> <li>▪ Occult blood loss.</li> <li>▪ Underlying hematologic diseases (i.e., thalassemia)</li> <li>▪ Vitamin deficiencies: (i.e., folic acid or vitamin B12)</li> </ul> <ul style="list-style-type: none"> <li>• Hemolysis.</li> </ul>	<p><b>patients</b> – PA required</p> <ul style="list-style-type: none"> <li>• Case by case review. Co-morbid conditions.</li> <li>• Hgb/Hct between 10 and 12 g/dl (30-36%) and a serum erythropoietin of less than 500 Mu/ml.</li> </ul> <p><b>Note</b> – In all cases the cause of the anemia is not due to correctable/treatable factors such as:</p> <ul style="list-style-type: none"> <li>▪ Iron deficiency (it is recognized that patients on darbepoetin may still require supplemental iron therapy.)</li> <li>▪ Underlying infectious or inflammatory processes.</li> <li>▪ Occult blood loss.</li> <li>▪ Underlying hematologic diseases (i.e., thalassemia)</li> <li>▪ Vitamin deficiencies: (i.e., folic acid or vitamin B12)</li> </ul> <ul style="list-style-type: none"> <li>• Hemolysis.</li> </ul>
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**PHC FORMULARY: ADDITIONS / CHANGES**  
**Effective 11-1-07**

DRUG	CLASS	FORMULARY STATUS	RESTRICTIONS / LIMITS
<b>ADDITIONS:</b>			
Clarithromycin /various	Antibiotic, macrolide	<b>Formulary, Code 1, QL</b>	Code 1: restricted to use for treatment of H. pylori Quantity limit: #28 (500 mg bid)
Lamictal (lamotrigine)/GSK; Teva	Anticonvulsant	<b>NF</b>	½ tablet substitution -25 mg (chewable) : use ½ tablet 50 mg -100 mg use ½ tablet of 200 mg - 50 mg use ½ tablet of 100 mg POS messaging: submit TAR with ½ tablet substitution
<b>DELETIONS</b>			
None			